

REMARKS

Claims 1-15 are pending. Claims 3 and 8 are currently canceled. Claims 1, 12, and 15 are currently amended. Reconsideration of the application is requested.

§ 112 Rejections

Claims 1-15 stand rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 1 and 12 have been amended to delete “physiologically functional derivative”. Claim 15 has also been amended to correct what appears to have been a clerical error.

~~<OPTIONAL>~~ **§ 103 Rejections**

Claims 1-9, 13 and 15 stand rejected under 35 USC § 103(a) as being unpatentable over McNamera (WO 99/65464) in view of Oliver et al. (U.S. Patent No. 6,120,752) and Oliver et al.(U.S. Patent No. 6,054,488).

Applicants respectfully submit that one skilled in the MDI art would not, without using hindsight, made the combination of McNamera, Oliver, and Oliver-488 laid out by the Examiner. Also, there would not have been a reasonable expectation of success that formoterol in suspension and ciclesonide in solution would form a chemically and physically stable HFA MDI formulation. Drug-drug interactions are well known and expected in pharmaceutical formulations. Stability is the exception and not the expectation.

Accordingly, it is submitted that a prima facie case of obviousness is not supported by the asserted combination, and withdrawal of the rejection is requested.

Claims 10-12 stand rejected under 35 USC § 103(a) as being unpatentable over McNamera (WO 99/65464) in view of Oliver et al. (U.S. Patent No. 6,120,752) and Oliver et al.(U.S. Patent No. 6,054,488) as applied to claims 1-9, 13, and 15 above, and further in view of Jinks et al. (WO 02/30394).

The four-way combination with the addition of Jinks et al. for the disclosure of bulking agent once again requires impermissible hindsight reconstruction of the claimed invention. One

skilled in the art would not have had a reasonable expectation of success that formoterol suspension and ciclesonide solution can be formulated with bulking agent as chemical and physically stable HFA MDI product. Reconsideration and withdrawal are therefore respectfully requested.

Claim 14 stands rejected under 35 USC § 103(a) as being unpatentable over McNamera (WO 99/65464) in view of Oliver et al. (U.S. Patent No. 6,120,752) and Oliver et al. (U.S. Patent No. 6,054,488) as applied to claims 1-9, 13, and 15 above and further in view of Ashurst (U.S. Patent No. 6,131,566).

Ashurst discloses certain fluoropolymer coatings but does not disclose a combination of formoterol suspension and ciclesonide solution. Again, as set forth above, to arrive at the claimed invention requires hindsight reconstruction from no less than four separate pieces of prior art. It is respectfully submitted that one skilled in the art would not have made the asserted combination and would not have had a reasonable basis for expectation of success in terms of chemical and physical stability.

In view of the above, it is submitted that the application is in condition for allowance. Reconsideration of the application is requested.

Respectfully submitted,

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